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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,227	05/31/2001	Hector F. DeLuca	1256-00765	1698

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Thomas M. Wozny  
Andrus, Sceales, Starke & Sawall, LLP  
100 East Wisconsin Avenue, Suite 1100  
Milwaukee, WI 53202

EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/871,227

Applicant(s)

DELUCA ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.    | 6) <input type="checkbox"/> Other:  |

## First Office Action on the Merits

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4 and 9-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 7 and 12-20 of U.S. Patent No. 5,945,410. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed compounds are either encompassed or made obvious by the cited patent.

The instant claims are drawn to isomeric forms of 19-nor-2-ethyl-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub>. The cited patent teaches a genus of 19-nor-2-alkyl-vitamin D compounds and exemplifies isomeric forms of 19-nor-2-methyl-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub> (see especially, col. 28, claims 12-15). The compounds exemplified by the reference are adjacent lower homologs of the instantly claimed compounds. Thus, the close structural similarity of the exemplified prior art compounds makes obvious to the skilled

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artisan the claimed compounds. The skilled artisan would expect adjacent homologs to have properties and, thus, similar use as taught by the reference.

3. Claims 5-8 and 33-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 7 and 12-16 of U.S. Patent No. 5,843,928. Although the conflicting claims are not identical, they are not patentably distinct from each other because claimed compound is either encompassed or made obvious by the cited patent.

The instant claims are drawn to isomeric forms of 19-nor-2-ethylidene-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub>. The cited patent teaches a genus of 19-nor-2-alkylidene-vitamin D compounds and exemplifies isomeric forms of 19-nor-2-**methylene**-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub> (see especially, col. 27, claims 12-13). The compounds exemplified by the reference are adjacent lower homologs of the instantly claimed compounds. Thus, the close structural similarity of the exemplified prior art compounds makes obvious to the skilled artisan the claimed compounds. The skilled artisan would expect adjacent homologs to have properties and, thus, similar use as taught by the reference.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4 and 9-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. ('410).

The instant claims are drawn to isomeric forms of 19-nor-2-ethyl-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub> and composition containing said compounds.

DeLuca et al. teach a generic group of 2-alkyl-19-nor-vitamin D compounds and exemplifies isomeric forms of 19-nor-2-**methyl**-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub> (see the entire article, especially col. 1, line 15 – col. 3, line 65; claims 1, 2, 7 and 12-15). The reference teaches the compounds are characterized by low intestinal calcium transport activity and high bone calcium mobilization activity and, thus, are useful for treatment of diseases where bone formation is desired (see especially Abstract, col. 3, line 66 – col. 4, line 16; col. 4, lines 21-37). The reference also teaches amounts from 0.01  $\mu$ g/gm to about 100  $\mu$ g/gm and various routes of administration (see especially, col. 4, lines 17-20, 37-42, claims 16-20).

The instant claims differ from the reference by reciting isomeric forms of a compound not exemplified by the reference. However, the compounds exemplified by the reference, i.e., isomeric forms of 19-nor-2-**methyl**-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub>, are adjacent lower homologs of the claimed compounds. Thus, the close structural similarity of the exemplified prior art compounds makes the claimed compounds obvious to the skilled artisan. In addition, the reference teaches **ethyl** as alkyl substituent in the 2-position (see col. 5, lines 40-46). Therefore, substitution of ethyl for methyl in the compounds exemplified by the reference would be prima facie obvious. The motivation

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is based on the desire to make additional compounds as taught by the reference for use in treating diseases such as osteoporosis, osteomalacia etc.

6. Claims 5-8 and 33-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. ('928).

The instant claims are drawn to isomeric forms of 19-nor-2-ethylidene-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub> and composition containing said compounds.

DeLuca et al. teach a generic group of 2-alkylidene-19-nor-vitamin D compounds and exemplifies isomeric forms of 19-nor-2-**methylene**-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub> (see the entire article, especially col. 2, line 33 – col. 3, line 65; claims 1, 2, 7, 12 and 13).

The reference teaches the compounds are characterized by low intestinal calcium transport activity and high bone calcium mobilization activity and, thus, are useful for treatment of diseases where bone formation is desired (see especially Abstract, col. 4, lines 6-26, 30-47). The reference also teaches amounts from 0.01  $\mu$ g/gm to about 100  $\mu$ g/gm and various routes of administration (see especially, col. 4, lines 26-29, 47-52; claims 14-16).

The instant claims differ from the reference by reciting isomeric forms of a compound not exemplified by the reference. However, the compounds exemplified by the reference, i.e., isomeric forms of 19-nor-2-**methylene**-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub>, are adjacent lower homologs of the claimed compounds. Thus, the close structural similarity of the exemplified prior art compounds makes the claimed compounds obvious to the skilled artisan. In addition, the reference teaches **ethylene** as alkylidene

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substituent in the 2-position (see col. 6, lines 41-47). Therefore, substitution of ethylene for methylene in the compounds exemplified by the reference would be prima facie obvious. The motivation is based on the desire to make additional compounds as taught by the reference for use in treating diseases such as osteoporosis, osteomalacia etc.

### ***Other Matters***

7. The data presented in Table 1 on pages 23-24 of the present specification is noted. However, the comparison is not with the closest prior art compounds, i.e., the isomers of 19-nor-2-**methyl**-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub> and 19-nor-2-**methylene**-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub> taught by DeLuca et al. ('410 and '928) and, thus, the results are not considered unobvious and/or unexpected.

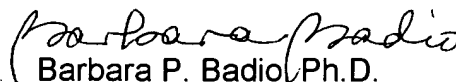
### ***Telephone Inquiry***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in cursive script, reading "Barbara P. Badio".

Barbara P. Badio, Ph.D.

Primary Examiner

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BB

November 14, 2002